

**ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS CONGESTION AND  
COUGH DAY AND NIGHT- acetaminophen, dextromethorphan hydrobromide, doxylamine  
succinate, phenylephrine hydrochloride  
Bayer HealthCare LLC.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day & Night Liquid Gels**

**Do not take these products at the same time.**

***Drug Facts***

**Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day Liquid Gels**

***Active ingredients (in each capsule)***

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

***Purposes***

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

***Uses***

- temporarily relieves these symptoms due to a cold or flu:
- nasal congestion · sinus congestion and pressure
- headache · minor aches and pains
- cough · sore throat
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

***Warnings***

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives
- facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

**Ask a doctor before use if you have**

- liver disease • heart disease • high blood pressure
- thyroid disease • diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

**When using this product** do not exceed recommended dosage

**Stop use and ask a doctor if**

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

***Directions***

- do not take more than the recommended dose

- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- children under 12 years: do not use

## **Other information**

### ***Other information***

- store at room temperature. Avoid excessive heat above 40°C (104°F).

***Inactive ingredients*** FD&C yellow #6, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

## **Questions or comments?**

***Questions or comments?*** 1-800-986-0369 (Mon-Fri 9AM –5PM EST)

**Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Night Liquid Gels**

### ***Drug Facts***

#### ***Active ingredients (in each capsule)***

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

#### ***Uses***

- temporarily relieves these symptoms due to a cold or flu:
- nasal congestion · sinus congestion and pressure
- headache · minor aches and pains
- cough · sore throat
- runny nose · sneezing
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

#### **Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening · blisters · rash · hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use to sedate children.**

**Ask a doctor before use if you have**

- liver disease • heart disease • high blood pressure
- thyroid disease • diabetes • glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

**When using this product**

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

- nervousness, dizziness, or sleeplessness occurs

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.
- children under 12 years: do not use

## Other information

### Other information

- store at room temperature. Avoid excessive heat above 40°C (104°F).

**Inactive ingredients** FD&C blue #1, D&C yellow #10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

## Questions or comments?

**Questions or comments?** 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

**Alka-Seltzer PLUS**

**MAXIMUM STRENGTH**

**Severe Sinus Congestion & Cough**

**DAY NON-DROWSY**

**NIGHT**

**ACETAMINOPHEN / Pain Reliever-Fever Reducer**  
Dextromethorphan HBr / Cough Suppressant  
Phenylephrine HCl / Nasal Decongestant

▶ Nasal & Sinus Congestion  
▶ Sinus Pressure  
▶ Headache & Body Ache  
▶ Cough

**12 LIQUID GELS**  
(Liquid Filled Capsules)

**ACETAMINOPHEN / Pain Reliever-Fever Reducer**  
Dextromethorphan HBr / Cough Suppressant  
Doxylamine Succinate / Antihistamine  
Phenylephrine HCl / Nasal Decongestant

▶ Sinus Congestion & Pressure  
▶ Headache & Pain  
▶ Runny Nose & Sneezing  
▶ Cough

**8 LIQUID GELS**  
(Liquid Filled Capsules)

**Do not take these products at the same time.**

**Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day Liquid Gels**

Drug Facts	Purposes
<b>Active ingredients (in each capsule)</b>	
Acetaminophen 325 mg	Pain reliever/fever reducer

**Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Night Liquid Gels**

Drug Facts	Purposes
<b>Active ingredients (in each capsule)</b>	
Acetaminophen 325 mg	Pain reliever/fever reducer



Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

Dextromethorphan hydrobromide 10 mg ..... Cough suppressant  
Doxylamine succinate 6.25 mg ..... Antihistamine  
Phenylephrine hydrochloride 5 mg ..... Nasal decongestant

### Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day Liquid Gels

#### Drug Facts (continued)

##### Uses

- temporarily relieves these symptoms due to a cold or flu:
  - nasal congestion
  - headache
  - cough
  - sinus congestion and pressure
  - minor aches and pains
  - sore throat
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

##### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- facial swelling
- asthma (wheezing)
- rash
- hives
- shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

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### Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Night Liquid Gels

#### Drug Facts (continued)

##### Uses

- temporarily relieves these symptoms due to a cold or flu:
  - nasal congestion
  - headache
  - cough
  - sinus congestion and pressure
  - minor aches and pains
  - sore throat
  - sneezing
- helps clear nasal passages and shrinks swollen membranes
- temporarily reduces fever

##### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
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- rash
- hives
- shock

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**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use to sedate children.**

3/4

8 1/2

3/4

Cut Edge

### Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Day Liquid Gels

#### Drug Facts (continued)

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

##### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

##### Ask a doctor before use if you have

- liver disease
- heart disease
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- high blood pressure
- diabetes
- glaucoma

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin

### Alka-Seltzer Plus® Maximum Strength Severe Sinus Congestion & Cough Night Liquid Gels

#### Drug Facts (continued)

##### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

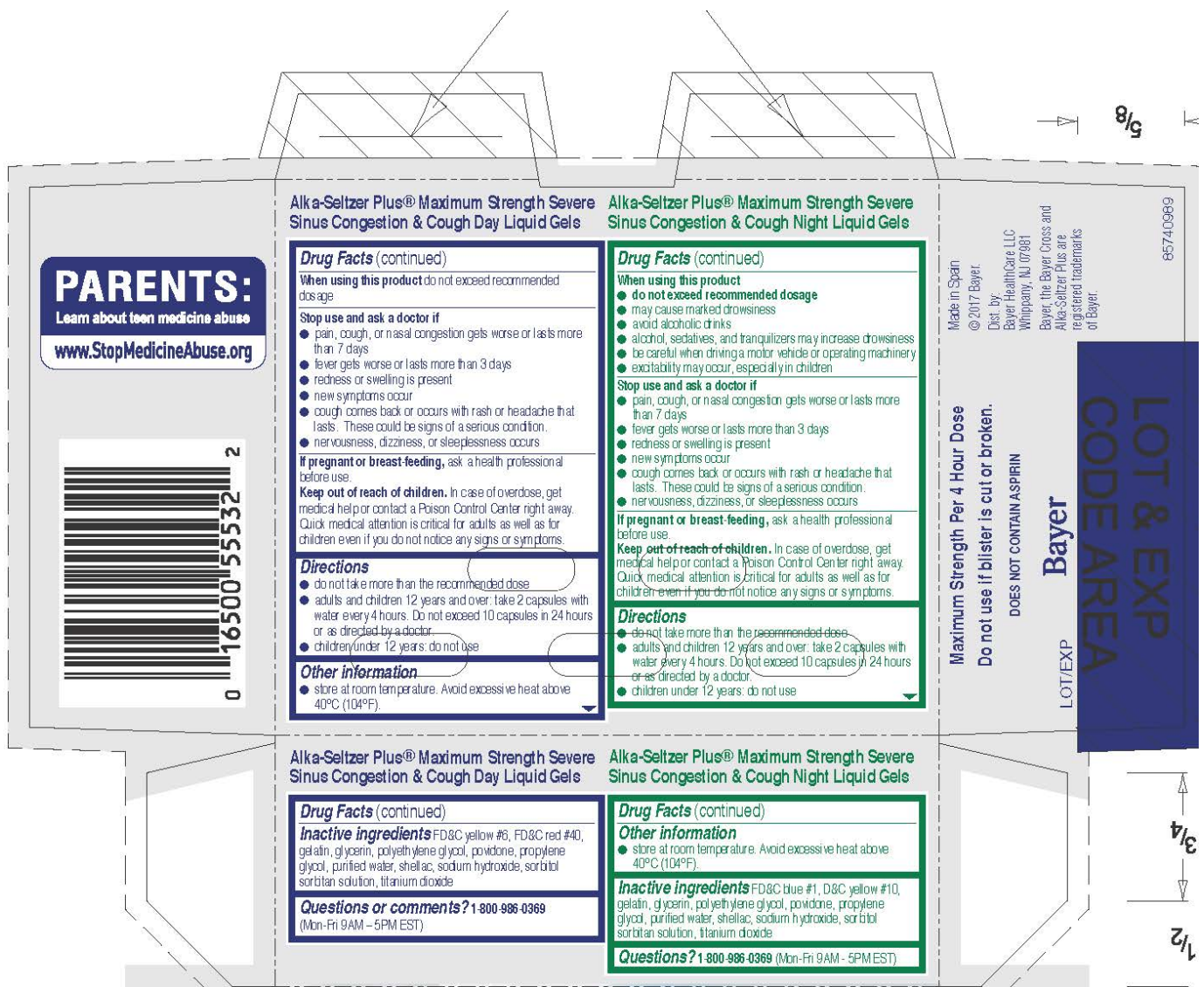
##### Ask a doctor before use if you have

- liver disease
- heart disease
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- high blood pressure
- diabetes
- glaucoma

##### Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

INSIDE of EC Flap



## ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS CONGESTION AND COUGH DAY AND NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-1610
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1610-20	1 in 1 CARTON; Type 0: Not a Combination Product	06/12/2017	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	4 BLISTER PACK	16

Part 1 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS CONGESTION AND COUGH DAY

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	AS;SC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/12/2017	

Part 2 of 2

ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS CONGESTION AND COUGH NIGHT

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	Score	no score
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<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	AS;SC
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
1		2 in 1 CARTON	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	06/12/2017	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	06/12/2017	

**Labeler** - Bayer HealthCare LLC. (112117283)